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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,647	01/07/2002	Toni Marie Antalis	11168A	3669

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EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/040,647	Applicant(s) ANTALIS ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on RCE request filed 9/11/2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 68, 71, 74-76 and 78-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68, 71, 74-76, 78, 79, 81 and 83 is/are rejected.
- 7) ☒ Claim(s) 80 and 81 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/723,942.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>filed 9/11/06. Duplicate of 1449 from</u>                     | 6) <input type="checkbox"/> Other: _____                          |

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**A request for continued examination (RCE)** under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/2006 has been **entered**.

Claims 1-67, 69-70, 72-73, 77 have been canceled. Claims 68, 71, 74-76, 78 and newly presented claims 79-83 are still at issue and are present for examination.

Applicants' arguments filed on 9/11/2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### ***Information Disclosure Statement***

The standard and formal 1449 form, filed 9/11/2006 containing identical references filed on informal 1449 form, has been considered and initialed.

#### ***Claim Objections***

With respect to objection held against claim 78 applicant responded that he/she has amended the claim and has written it in an independent form to render it allowable and therefore the objection should be withdrawn. This argument was fully considered but was found **unpersuasive** because even though applicant has amended claim 78 to be independent, he/she also added the phrase "fragments thereof" to said claim and said phrase renders the claim subject to written description rejection (shown below).

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Claims 68 and 74 are objected to because of the following informalities: The term "complimentary" in said claims is incorrectly spelled. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68, 71, 74-76, 78-79, 81, 83 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention according to previous office actions. In traversal of this rejection applicant argues that in view of interview summary held between applicant and the examiner of record on 2/9/2006, he/she has amended the claims to recite the specific parameters of high stringency conditions and indicates that according to current state of the art, stringency temperature, indicated by the examiner to be too low to result in adequately described products, alone, is not a conclusive factor for the degree of stringency and rather it is the combination of salt and temperature conditions which define the structure of DNA sequences under coordination. Therefore, in view of applicant, the amended claims have overcome the rejection and it should be withdrawn.

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These arguments were fully considered but were found **unpersuasive**. This is because even though applicant amended the claim to recite the exact salt and temperature conditions used said conditions, that is temperate together with salt and detergent concentrations used and not temperature alone remain to be too broad to allow for hybridization of DNA products which are sufficiently well defined as indicated by the examiner previously. Therefore the claims remain rejected for the reasons of record.

In addition applicant is reminded that instant claims are even more subject to lack of adequate written description due to the recitation of the totally broad phrase "fragments thereof" for which no specific definition is provided in the disclosure. Therefore, any genus of polypeptide consisting of at least 3 amino acids can be considered to be a fragment of claimed products. The disclosure fails to provide any structural (and in some cases even functional information) about the structure of genera of fragments of both the expression products of SEQ ID NO:5 and variants thereof such that one of skill in the art could recognize the members of said genus and distinguish them from those belonging to other polypeptides. Given the breadth of said phrase and the absence of any activity recitation one of skill in the art needs to know which regions or specific amino acids must be retained such that the members of said genera could be distinguished from those belonging to others. Currently no such information can be found in the disclosure. All applicant provides is the expression product of SEQ ID NO:5 which fails to put the skilled artisan in full possession of the genera as broadly claimed.

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It should be noted that in cases where some activity is recited for fragments (see for example claim 79 and 81) said genera remain rejected for failing to provide adequate structural information about the fragments that retain serine proteins activity.

Therefore applicant's amendment not only does not overcome the previous rejection but asks for even more written description for the reasons stated above and therefore the rejections maintained.

Claims 68, 71, 74, 75, 76, 78, 83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polypeptides encoded by SEQ ID NO:5, does not reasonably provide enablement for fragments of said expression products or fragments of the variants of said expression products with no proteins activity.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which residues in claimed fragments is in charge of assigning function to SEQ ID NO:6 fragments or variant of SEQ ID NO:6 fragments. No examples of such residues are not provided either. Current state of the art indicates that many fragments of a full-length polypeptide are totally incapable of retaining any function corresponding to said full-length polypeptide.

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Therefore, due to lack of sufficient guidance and examples provided and due to unpredictability of prior art as to which residues within claimed fragments should be retained such that said products retain activity one of skill in the art has to go through the burden of undue experimentation in order to screen for those products that retain proteinase activity and as such the claims go beyond the scope of the disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 71, 75, 79, 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 71 (and its dependent claims 75, 79-80, 83) it is unclear how can both a full-length proteinaceous molecule and fragments thereof be set forth by a single amino acid sequence, namely the expression product of SEQ ID NO:5 or its variants. Appropriate clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68, 71, 74-76, 78, 79, 81, 83 are rejected under 35 U.S.C. 102(b) as being by Yu et al. (JBC, 270(22), 13483-13489, 1996). Yu (see the attached sequence alignment) discloses a polypeptide having serine protease activity whose sequence has 33.5% homology to residues 6-313 of SEQ ID NO:6 and can be considered to be

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fragment of SEQ ID NO:6 encoded by a sequence hybridizing to SEQ ID NO:5 of this invention under stringent conditions recited in claim 5, anticipating claims 68, 71, 78-79. In page 13484 column 1, Yu teaches about a human plasma (which can be considered to be a pharmaceutically acceptable carrier) comprising its wild type proteinase, wherein said proetinase by inherency is glycosylated, anticipating claims 74, 76, 81 and 83. In page 13483, column 2, Yu teaches about the expression product of its full-length cDNA and reducing and non-reducing buffers comprising said expression product, wherein said buffers can be considered to be compositions comprising said expression products with a pharmaceutically acceptable carrier, anticipating claim 75.

***Allowable Subject Matter***

Claims 80, 82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because SEQ ID NO:15-17 are free of prior art. Further the prior art does not teach or suggest such specifically claimed products. Hence said products are also non-obvious.

SEQ ID NO:6 remains allowed for the reasons record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kerr Kathleene can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshipouri

Maryam Monshipouri Ph.D.  
Primary Examiner

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